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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/834,424	04/13/2001	Stuart L. Schreiber	331D USD1	5917

7590

07/07/2003

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EXAMINER

VOGEL, NANCY S

ART UNIT

PAPER NUMBER

1636

14

DATE MAILED: 07/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/834,424

Applicant(s)

SCHREIBER ET AL.

Examiner

Nancy T. Vogel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

This action is in response to the amendment filed 8 April 2003, Paper No. 13, in which claims 1-7 were cancelled and claims 8-29 were added.

Claims 8-29 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Amendment

Applicant's submission of substituted pages 24a, 24b, 25a and 25b is acknowledged. This submission overcomes the objection made in the previous Office action, mailed 1 October, 2003, Paper No. 9.

Applicant's cancellation of claim 4, and submission of new claim 11 that recites the full names of abbreviated terms formerly present in claim 4, overcomes the objection to the claims made in Paper No. 9.

The rejections of claims 1-7 under 35 U.S.C. 102 (b) or (e), made in Paper No. 9, has been withdrawn in view of the cancellation of claims 1-7, and addition of new claims 8-29.

Claims 8-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection, originally applied to claims 1-7 in the previous Office action mailed 1 October 2003, Paper No. 9, still applies to newly submitted claims 8-29, and is maintained for reasons of record and as further discussed below.

The rejection of claims 1-7 under 35 U.S.C. 112, second paragraph, made in Paper No. 9, has been withdrawn in view of applicant's cancellation of claims 1-7, and addition of new claims 8-29.

Response to Arguments

With response to the rejection of claims 1-7 under 35 USC 112, first paragraph for lack of enablement, now applicable to newly submitted claims 8-29, Applicant's arguments filed 8 April 2003 in Paper No. 13 have been fully considered but they are not persuasive.

Applicants have argued that they have disclosed dimerizing agents having the characteristics recited in the new claims at pages 13-17 of the specification, The specification discloses a few candidate compounds, and suggests that any other

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compound that is known or found to bind to a receptor, may be encompassed by the claimed method. Applicants argue that therefore invention as claimed is fully described. They point to the work of other researchers, Tian and Qureshi, submitted as Exhibits A and B, which recognized that small non-peptide agents could be used to dimerize signal transduction components. However, this does not provide evidence that the inventors, at the time the application was filed, were in possession of the invention as claimed. It is noted that the non-peptidic binding small molecules taught by the references, in fact, aren't described in the instant specification, therefore their description by others is not relevant to the instant application. As previously stated in Paper No. 9, the disclosure is not descriptive of the complete structure of a representative number of species encompassed by the claims as one of skill in the art cannot envision all the non-peptidic compounds that may be found to bind to a receptor based on the teachings in the specification. There is no discussion of common structural feature(s) of the non-peptidic compounds that bind to any particular receptor. The fact that other workers in the field, long after the filing of the instant application, may have determined several non-peptidic compounds that could dimerize signal transduction components, does not provide any evidence that the instant specification reasonably conveys to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, especially since the cited references teach compounds not described by the instant specification. The genus of possible dimerizing agents which are non-peptidic, less than 5kD and/or membrane permeant contains millions of species that are unrelated in structure. There are not a

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representative number of species described in the specification, such that one could envision all of the species encompassed by the claimed genus. The rejection is maintained.

Conclusion

Claims 8-29 are rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy T. Vogel whose telephone number is (703) 308-4548. The examiner can normally be reached on 7:30 - 4:00, Monday - Friday.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

ntv
July 7, 2003


REMY YUCEL, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600